REMARKS

Responsive to the Office Action dated 10/3/01, applicants have further amended claims 1-4 and 7-9. Reconsideration is respectfully requested in view of the amendments and the following remarks.

Claims 1-4 and 7-9 are now pending.

Rejection under 35 U.S.C. 112, second paragraph:

The Examiner rejects claims 1-4 and 7-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner objects the use of "." after the method step letter "a", "b", etc. other than at the end of the claim, and the same letter designating multiple steps in the same claim, for example "a" for both "step a" and a subsequent step. Applicants have deleted the improper occurrence of "." and redesignated the method steps, therefore, obviated these objections.

The Examiner also suggests that the objection to the term "predetermined progressively increasing amounts" may be obviated by specifically reciting particular amounts of Product R used for the assay. Applicants have amended the above term as "predetermined progressively increasing amounts at concentrations between 0 to 100%, by volume". Further, the term "biologically acceptable pH range" has been amended as "physiologically acceptable pH range" to overcome the objection to the term "biologically".

Step h of claim 1 and step e of 7 have been further amended to indicate how the RT-PCT products are compared by reciting "comparing each said amount of said RT-PCR product produced from each said group with each other". Since the precedent steps recite that a

plurality groups of cells are treated with different amount of Product R, each group of the cells is thus expected to produce an amount of RT-PCR product correlating with the amount of Product R added to that group of cells. By comparing each such group of cells with each other, a person of ordinary skill in the art would be able to conclude whether the gene expression is down regulated by Product R or not, because it is a commonly known to a person of ordinary skill in the art that a lower relative amount of RT-PCR products correlates with a decreased gene expression and a higher amount correlates with an increased gene expression. This is evidently shown in Fig. 1 of the present application, which results from the gene expression of each group of cells having different Product R treatments. The determination of such regulation of gene expression is a result naturally flowing from such comparison. Making such a determination is merely a mental act, which does not involve any manipulative step. There is nothing more that needs to be done manually after the step of comparison is completed.

Accordingly, applicants respectfully submit that the rejection to claims 1 and 7 under 35 U.S.C. 112, second paragraph, has been overcome and should be withdrawn.

For the same reason, the rejection to claims 2-4, which depend on claim 1, and claims 8-9, which depend on claim 7, should also be withdrawn.

Rejection under 35 U.S.C. 112, first paragraph:

The Examiner rejects claims 1-4, and 7-9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which fit pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the Examiner states that there is insufficient guidance in the specification to allow a person of ordinary skill in the art to determine what

would constitute a "predetermined amount" of each reagent for the preparation of Product R. Applicant respectfully submits that the Examiner's statement is incorrect because the present application, on pages 9-11, provided two specific methods for preparing Product R, where the amount of each reagent for the preparation is given. Having had such a guidance, a person of ordinary skill in the art is fully capable of varying the relative amount of each reagent proportionally depending on the total amount of Product R to be prepared.

The Examiner further states that it remains unclear in what manner the RT-PCR products are compared and how that comparison would determine down regulation of gene expression of HIV- coreceptor. As discussed in connection with the rejection under 35 U.S.C. 112, second paragraph, claims 1 and 7 have been amended to specifically recite that the amount of RT-PCR products produced from each group cells treated with different amount of Product R is compared with each other, and evidently, a higher amount of RT-PCR products represents an increased gene expression.

In addition, the Examiner rejects the recitation of the same letter to designate multiple method steps. Also as discussed above, applicants have amended claims 1 and 7 to eliminate the recitation of the same letter in the same claim.

Accordingly, it is respectfully submitted that the rejection to claims 1 and 7 under 35 U.S.C. 112, first paragraph, has been overcome and should be withdrawn.

For the same reason, the rejection to claims 2-4, which depend on claim 1, and claims 8-9, which depend on claim 7, should also be withdrawn.

Allowance of claims 1-4 and 7-9 is respectfully requested.

It is believed that no fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,

COHEN, PONTANI, LIEBERMAN & PAVANE

By _____

Yunling Ren
Reg. No. 47,109
551 Fifth Avenue, Suite 1210
New York, New York 10176
(212) 687-2770

Dated: January 31, 2002

AMENDMENTS TO THE SPECIFICATION AND CLAIMS SHOWING CHANGES

In the Claims:

Please amend claims 1 and 7 as follows:

1. (Three-Time Amended) A method for determining down-regulation of gene expression of a human immunodeficiency virus (HIV) coreceptor, comprising the steps of:

a[.] culturing cells capable of expressing said human HIV coreceptor;

b[.] dividing said cultured cells into a plurality of groups;

c[.] introducing predetermined progressively increasing amounts of Product R at concentrations between 0 to 100%, by volume, to said plurality of groups of said cultured cells, respectively, by electroporation;

d[.] culturing said plurality of groups of said electroporated cells;

e[.] preparing a total RNA from each said group of said cultured electroporated cells after step d, respectively;

f[.] reverse-transcribing the mRNA of said HIV coreceptor from each said total RNA by a reverse transcription-polymerase chain reaction (RT-PCR) to produce an RT-PCR product;

g[.] measuring the amount of said RT-PCR product produced from each said group of said cells; and

h[.] comparing [the relative amounts] each said amount of said RT-PCR [products from said plurality of groups of said cells to determine the reduction of said RT-PCR product] product produced from each said group with each other, wherein Product R is made by a process comprising the steps of:

a'[a.] mixing predetermined amounts of casein, beef peptone, ribonucleic acid (RNA), bovine serum albumin and sodium hydroxide in a predetermined amount of water;

b'[b.] autoclaving the mixture from said step [a] a' until RNA is completely digested;

c'[c.] cooling the product from said step [c] b', said cooled product comprising solids;

d'[d.] removing said solids from the product from said step [c] c';

e'[e.] adding water to the product from said step [d] d'; and

f'[f.] adjusting the pH of the product from said step [e] e' to a [biological] physiologically acceptable pH range.

7. (Twice Amended) A method for determining down-regulation of gene expression of a human immunodeficiency virus (HIV) coreceptor, comprising the steps of:

a[.] dividing cells capable of expressing said human HIV coreceptor into a plurality of groups;

b[.] introducing predetermined progressively increasing amounts of Product R at concentrations between 0 to 100%, by volume, into said plurality of groups of said cells, respectively, by electroporation;

c[.] reverse-transcribing the mRNA of said HIV coreceptor of each said groups of said cells by a reverse transcription-polymerase chain reaction (RT-PCR) to produce an RT-PCR product;

d[.] measuring the amount of said RT-PCR product produced from each said group of said cells; and

e[.] comparing [the relative amounts] each said amount of said RT-PCR [products from said plurality of groups of said cells to determine the reduction of said RT-PCR product] product produced from each said group with each other, wherein Product R is made by a process comprising the steps of:

a'[a.] mixing predetermined amounts of casein, beef peptone, ribonucleic acid (RNA), bovine serum albumin and sodium hydroxide in a predetermined amount of water;

b'[b.] autoclaving the mixture from said step [a] a' until RNA is completely digested;

c'[c.] cooling the product from said step [c] b', said cooled product comprising solids;

d'[d.] removing said solids from the product from said step [c] c';

e'[e.] adding water to the product from said step [d] d'; and

f'[f.] adjusting the pH of the product from said step [e] e' to a [biological] physiologically acceptable pH range.